



[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2017-0043]

16 CFR Part 1112

CPSC Acceptance of Third Party Laboratories: Revision to the Notice of Requirements for Prohibitions of Children's Toys and Child Care Articles Containing Specified Phthalates

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking (NPR) would update the existing notice of requirements (NOR) for prohibitions of children's toys and child care articles containing specified phthalates that provide the criteria and process for Commission acceptance of accreditation pursuant to the Consumer Product Safety Act (CPSA). The proposed NOR would revise the current NOR to be consistent with the final phthalates rule, which is published elsewhere in this same issue of the *Federal Register* and will be codified in the Code of Federal Regulations (CFR).

DATES: Submit comments by [Insert date 75 days after publication in the *Federal Register*].

ADDRESSES: You may submit comments, identified by Docket No. CPSC- 2017-0043, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except

through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC-2017-0043, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Scott R. Heh, Project Manager, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-504-7646; email: sheh@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) established requirements concerning concentration limits for specified phthalates in children’s toys and child care articles. In this same issue of the *Federal Register*, the

Commission is publishing a final rule that changes some of the statutory phthalate restrictions currently in place pursuant to section 108(b)(3) of the CPSIA. 15 U.S.C. 2063c(a). The Commission's phthalates rule makes permanent the interim prohibition on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of diisononyl phthalate (DINP). The phthalates rule extends this prohibition to cover all children's toys and child care articles containing concentrations of more than 0.1 percent of DINP. The phthalates rule also lifts the interim prohibitions on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of di-n-octyl phthalate (DNOP) or diisodecyl phthalate (DIDP). In addition, the phthalates rule prohibits children's toys and child care articles that contain concentrations of more than 0.1 percent of diisobutyl phthalate (DIBP), Di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP). The permanent prohibitions on children's toys and child care articles that contain concentrations of more than 0.1 percent on the use of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP) in children's toys and child care articles in section 108 of the CPSIA are unchanged by the phthalate rule.

Because the phthalates rule revises the list of statutorily prohibited phthalates in children's toys and child care articles in section 108 of the CPSIA, this NPR proposes to amend the existing NOR for the prohibitions of children's toys and child care articles containing specified phthalates to reflect those changes.

B. Notice of Requirements

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program or, for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. The Commission's phthalates rule is considered a "consumer product safety standard." 15 U.S.C. 2063c(f). Thus, products subject to the phthalates rule are subject to the testing and certification requirements of section 14 of the CPSA.

Because children's toys and child care articles are children's products, samples of these products must be tested by a third party conformity assessment body whose accreditation has been accepted by the Commission. These products also must comply with all other applicable CPSC requirements, such as the lead content requirements of section 101 of the CPSIA, the requirements of the toy standard, 16 CFR part 1250, and the tracking label requirement in section 14(a)(5) of the CPSA.

In accordance with section 14(a)(3)(B)(vi) of the CPSIA, the Commission has previously published two NORs for accreditation of third party conformity assessment bodies for testing children's toys and child care articles under section 108 of the CPSIA (76 FR 49286 (Aug. 10, 2011), 78 FR 15836 (March 12, 2013)).

If the Commission finalizes the NOR as proposed, the following process would be used during the transition period from test method CPSC-CH-C1001-09.3 (2010) to a

revised version of the method, currently titled, draft test method CPSC-CH-C1001-09.4 (2017). CPSC would accept testing to support children's toys and child care article certifications to the new phthalates prohibitions if the laboratory is already CPSC-accepted to test to CPSC-CH-C1001-09.3 (2010). Laboratories that conduct testing to support product certifications to the new phthalates prohibitions must list in their test reports "16 CFR part 1307" and CPSC-CH-C1001-09.3 until laboratories have transitioned their accreditation scope and CPSC listing to CPSC-CH-C1001-09.4.

The CPSC would open the laboratory application process for draft test method CPSC-CH-C1001-09.4 (2017) on the date the final NOR rule is published in the *Federal Register*. Laboratories that seek CPSC acceptance to the revised prohibitions for children's toys and child care articles in 16 CFR part 1307 would be required to update their accreditation scope. To be CPSC-accepted, a laboratory's scope of accreditation must include the reference to draft CPSC-CH-C1001-09.4 (2017). Laboratories that are currently CPSC-accepted to CPSC-CH-C1001-09.3 (2010) would be instructed to update their accreditation scope to include draft CPSC-CH-C1001-09.4 (2017) as soon as possible, and submit their application for CPSC acceptance. Laboratories that were not previously CPSC-accepted to CPSC-CH-C1001-09.3 (2010) would be instructed to work with their accreditation bodies to include "CPSC-CH-C1001-09.4 (2017)" in their scope documents.

CPSC would accept testing results to the new phthalates prohibitions in 16 CFR part 1307 from laboratories that are CPSC-accepted to CPSC-CH-C1001-09.3 (2010) for two years from the date of publication of the final rule NOR in the *Federal Register*. This should allow adequate time for laboratories to work with their accreditation bodies

to make official updates to their accreditation scope document to include the revised CPSC method “CPSC-CH-C1001-09.4 (2017)” and submit applications to the CPSC. Two years after the date the final rule NOR publishes in the *Federal Register*, the CPSC will no longer accept laboratory applications that reference CPSC-CH-C1001-09.3 (2010), and any application to CPSC must reference “CPSC-CH-C1001-09.4 (2017).”

C. Description of the Proposed Rule

The proposed rule would amend 16 CFR § 1112(b)(31), (31)(i) and (c)(3)(i) to update the references to reflect the promulgation of 16 CFR part 1307 and draft CPSC test method CPSC-CH-C1001-09.4 (2017). The draft test method would provide detailed information on testing that will be used by the CPSC testing laboratory for the analysis of phthalate content in children’s toys and child care articles. CPSC staff has determined that using an appropriate combination of the methods of extraction and analysis presented in the test method is sufficient to determine the concentration of the regulated phthalates in most children’s toys and child care articles. The general approach is to dissolve the sample completely in tetrahydrofuran, precipitate any PVC polymer with a second solvent, then analyze by Gas Chromatography-Mass Spectrometry (GC-MS). The draft test method provides definitions, a list of equipment and supplies needed for testing, procedures to measure phthalate concentration, instructions for sample preparation, and descriptions of the phthalate extraction method and instrument parameters. The draft test method is available at Tab A of the CPSC staff’s briefing package available on CPSC’s website at: https://www.cpsc.gov/s3fs-public/Notice%20of%20Proposed%20Rulemaking%20for%20NOR%20for%20Phthalates%20-%20September%202013%202017.pdf?ph5_n4seuAb0.USRYqPfsnmLuTKC8F_2.

Draft CPSC test method CPSC-CH-C1001-09.4 (2017) has been updated to reflect the list of phthalates prohibited in children's toys and child care articles in 16 CFR part 1307 ((di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), di-*n*-octyl phthalate (DNOP) diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP)). The draft test method CPSC-CH-C1001-09.4 (2017) is substantially the same as the current testing procedure. The Commission encourages comments on draft CPSC test method CPSC-CH-C1001-09.4 (2017). We note that the draft test method could change in the final rule.

D. Effective Date

The APA generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the proposed rule would allow testing to continue under the existing testing method by testing laboratories that meet certain criteria for a period of up to two years after the publication of a final rule, the Commission proposes a 30 day effective date for the final rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the APA, or any other statute, unless the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603 and 605. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The impact of the proposed rule on small testing laboratories would be minimal. The only laboratories that would be impacted are those that offer to test children's toys

and child care articles for prohibited phthalates. These laboratories are already accredited by one or more accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) and have had their accreditations accepted by the Commission. These laboratories would have to revise their procedures for testing for phthalate content to be consistent with the revised phthalate test method (CPSC-CH-C1001-09.4) which would replace the current phthalate test method (CPSC-CH-C1001-09.3) if the proposed NOR is finalized. Staff expects that the impact of revising testing procedures will be low for qualified laboratories because the same sample preparation, extraction methods, and equipment is used for both methods. Moreover, the additional phthalates included in draft CPSC-CH-C1001-09.4 can be isolated at unique elution times by gas chromatography and, therefore, the analysis should not be a burden for those qualified to perform such testing.

Additionally, within two years of the publication of the final NOR rule, laboratories would need to update their scope accreditation documents to include the revised phthalate test method (CPSC-CH-C1001-09.4). Staff expects that the burden of this requirement will also be low because testing laboratories typically must undergo a reassessment every two years in order to maintain their accreditations. Updating the accreditation scope documents to include the revised phthalate test method is a minor change and should result in little or no additional cost to a testing laboratory if completed during the periodic reassessment, which the 2-year window would allow testing laboratories to do.

After considering the economic impacts of this proposed rule on small entities, the Commission certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

F. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

List of Subjects in 16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Incorporation by reference, Reporting and recordkeeping requirements, Third party conformity assessment body.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 CFR chapter II, as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by:

a. Revising the introductory text to paragraph (b)(31);

- b. Revising paragraph (b)(31)(i); and
- c. Revising paragraph (c)(3)(i).

The revisions read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(31) 16 CFR part 1307, Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates. For its accreditation to be accepted by the Commission to test for phthalates in children’s toys and child care articles, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:

(i) CPSC Test Method CPSC-CH-1001-09.4, “Standard Operating Procedure for Determination of Phthalates;

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(c) * * *

(3) * * *

(i) CPSC-CH-C1001-9.4, “Standard Operating Procedure for Determination of Phthalates”, September 1, 2017.

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Alberta E. Mills,
Acting Secretary
U.S. Consumer Product Safety Commission

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